Abstract

U.S. Food and Drug Administration (FDA) approval is currently being sought for the use of chloramine-T as a waterborne therapeutant in aquaculture to control mortality associated with bacterial gill disease in cultured freshwater fish. We reviewed and characterized potential impacts, and environmental fate and effects of chloramine-T discharge into freshwater ecosystems after aquaculture use. The review represents only a portion of the FDA requirements to assess environmental safety. Our risk characterization integrates 1) available fate and effects data, 2) a recent USGS survey that detailed the projected use and discharge patterns of chloramine-T at U.S. aquaculture facilities, and 3) chloramine-T effluent monitoring following typical production raceway treatments. We modeled potential environmental effects of chloramine-T based on estimated environmental introduction concentrations (EIC) because of the lack of available degradation data and because chloramine-T may be regarded as total residual chlorine (TRC). Available data suggest that chloramine-T is much less toxic than TRC.

Methods

A. Define and validate environmental model to predict Cl-T concentrations that may be discharged into freshwater lentic or lotic systems after aquaculture use.

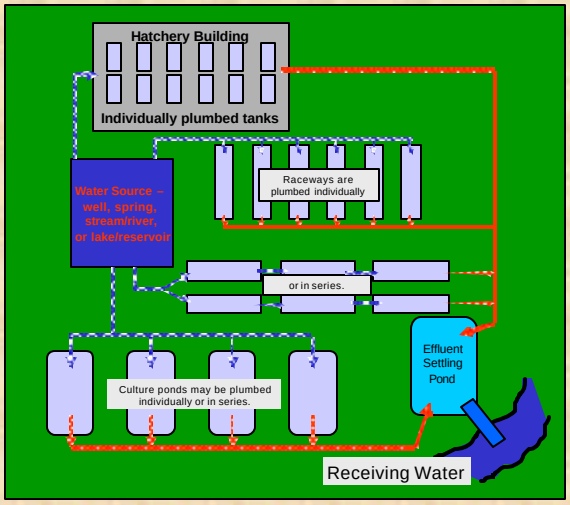
1. Summarize **Hatchery Survey** data from 100 public (state and federal), tribal, and private U.S. fish hatcheries including projected Cl-T treatment patterns.
2. Develop predictive models of Cl-T discharge concentration (**Environmental Introduction Concentration**; EIC) in hatchery effluent based on the surveyed hatcheries.
3. **Model Validation** to assure the accuracy of the predictive Cl-T effluent discharge model in a controlled setting.

B. Evaluate potential impacts, environmental fate and effects of Cl-T discharge.

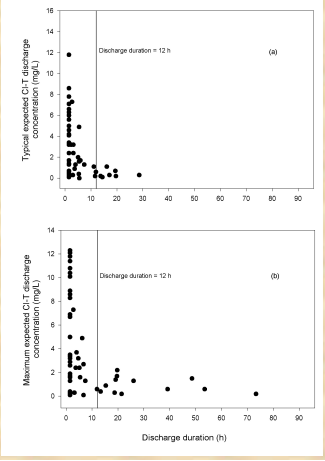
1. Review and summarize public literature describing Cl-T **Environmental Fate** and degradation.
2. Review and summarize public literature describing Cl-T **Environmental Effects**.

C. Characterize the risk associated with Cl-T discharge.

1. Integrate the predicted Cl-T discharge concentrations with the available effects data to develop a **Risk Assessment** of the relative risk of Cl-T use.



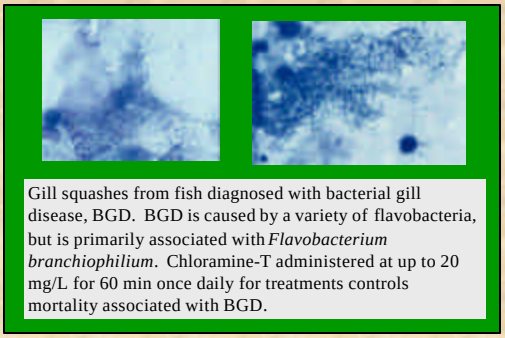
A.1. Diagram of a typical freshwater fish hatchery.



A.2. Environmental introduction concentration estimates determined using assumptions for typical (*a*) or maximum (*b*) treatment scenarios versus estimated discharge duration.

Proposed Use

U.S. Food and Drug Administration approval is presently being sought for the use of chloramine-T (Cl-T) as a waterborne therapeutant in aquaculture to control mortality associated with bacterial gill disease in cultured fresh-water fish. Outside the United States, Cl-T is used in Canada, Scotland, Ireland, Norway, and Chile to treat external bacterial infections on cultured fish.



Gill squashes from fish diagnosed with bacterial gill disease, BGD. BGD is caused by a variety of flavobacteria, but is primarily associated with *Flavobacterium branchiophilium*. Chloramine-T administered at up to 20 mg/L for 60 min once daily for treatments controls mortality associated with BGD.

A.1. *Hatchery Survey*

Water use.

- Median typical hatchery water flow was 12.5 million L/day
- Median low hatchery water flow was 6.1 million L/day
- 51 hatcheries used settling ponds (median settling pond volume was ~3.5 acre-feet) before discharge
- 77 hatcheries discharge into rivers, 14 into lakes, and 8 discharged into the backwaters of a river

Chloramine-T use.

- 61 hatcheries had or planned to use Cl-T, most at 20 mg/L.
- The average hatchery would administer 10 four-treatment regimens per year (~40 discharge events per year)

A.2. *Environmental Introduction Concentrations*

Predicting EICs.

- Assumptions
  - no degradation within the hatchery effluent
  - typical EIC produced at typical hatchery flow; maximum EIC at low hatchery flow
  - the chemical "slug" dispersed into a volume equal to 1.5 times the treatment duration
  - treatment concentration = 20 mg/L
- Formula

$$\frac{20\ \text{mg/L} * \text{treated volume}}{\text{hatchery flow rate} * 1.5 * \text{treatment duration}}$$

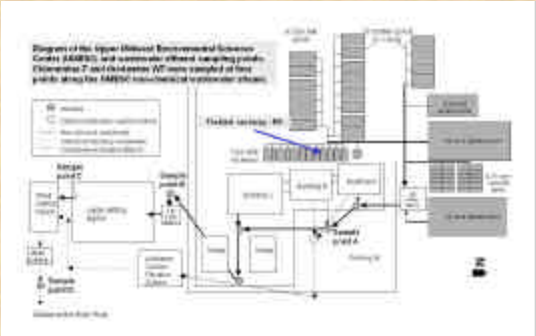
Estimated EICs.

- Hatcheries were categorized as short (<12 h) or long (>12 h) dischargers.
- Median EIC and ~95% confidence intervals developed for both typical and maximum EIC estimates

A.2. Estimated median typical or maximum environmental introduction concentration (EIC; mg/L) and discharge duration (h) and their ~95% confidence interval (CI; *in parentheses*) on the basis of hatchery water flow and chloramine-T treatment data from hatcheries surveyed in a recent USGS hatchery survey.

Typical or maximum EIC	Discharge <12 h or >12 h	Sample size (n)	EIC (mg/L)	Discharge duration (h)
Typical	<12	47	1.7 (1.1-3.4)	1.5 (1.5-2.4)
	>12	14	0.1 (0.0-0.3)	19.4 (14.4-246
Maximum	<12	42	3.1 (1.7-5.0)	1.5 (1.5-1.5)
	>12	19	0.3 (0.0-1.3)	23.7 (18.7-73.3)

A.3. *Model Validation*



Effluent concentrations of chloramine-T were measured after administering a standard treatments to a production style raceway.

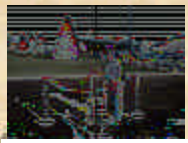
- Assumptions
  - same as predicted EIC
  - charged flow-through treatments are the worst case

Treatment conditions:

- Raceway volume = 7750 L
- Raceway flow rate = 267 L/min
- Four treatments administered once daily on consecutive days

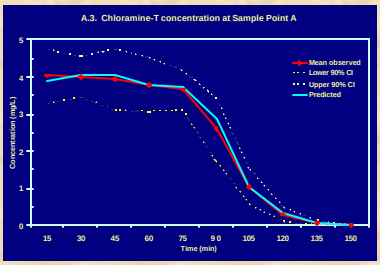
20 mg/L Cl-T treatment administered for 60 min

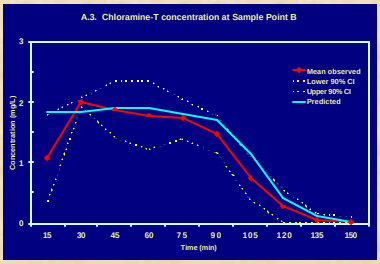
Cl-T samples processed by Hach DPD colorimeter



Sample Point A, flow rate = 1373 L/min

Sample Point B, flow rate = 2910 L/min



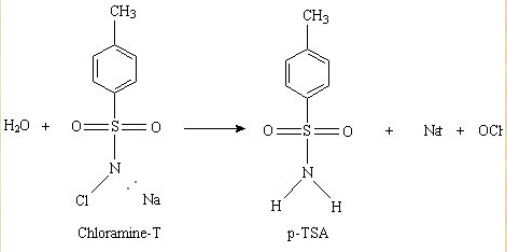


B.1. *Environmental Fate*

Chloramine-T is naturally dechlorinated to para-toluenesulfonamide (p-TSA) and by chlorine exchange to (usually mono-) chlorinated organic compounds, each at low concentrations.

Degradation of chloramine-T at the maximum EIC:

- does not produce aqueous free chlorine at concentrations of concern for aquatic toxicity
- does not produce inorganic (ammonia) chloramine in treatment or receiving waters
- is not known to produce potentially mutagenic electrophilic organochlorines, such as the trihalomethanes



B.1. The reduction of chloramine-T (N-chloro-p-toluenesulfonamide sodium salt) to p-TSA (p-toluenesulfonamide) in water

B.2. *Environmental Effects*

Species	Endpoint	Concentration (mg/L)	Comment
Green algae	48 h EC_{50}	0.31	Growth inhibition
Daphnia magna	24 h EC_{50}	4.8	Immobilization
Fish (rainbow trout, channel catfish, hybrid striped bass)	24 h LC_{50}	2.8 to > 80	Mortality in three species at various water chemistries

C. *Risk Assessment*

The risk of acute effects associated with chloramine-T discharge was estimated by the risk quotient (RQ) analysis. The RQ value is calculated by dividing the EIC by the acute LC_{50} value:

$$RQ = EIC/LC_{50}$$

If the RQ is:

- RQ > 0.5, presume unacceptable risk
- 0.1 < RQ < 0.5 risk may be mitigated by restricted use
- RQ < 0.1 presume no hazard (for endangered species use 0.05)

C.1. *Risk Assessment*

Species	Risk Quotient	Comment
Green algae	10.97	The risk quotients assume no degradation and are based on exposures up to 20 times the typical estimated discharge duration
Daphnia magna	0.71	
Fish	1.17 to <0.04	

Summary

Under use practices at most hatcheries, we believe that the use of chloramine-T as a waterborne drug to control bacterial gill disease constitutes no actual threat to the environment, the populations of organisms residing there, or public health and safety. Additional data on degradation from chlorine demand and toxicity to aquatic organisms would be useful to refine the risk assessment.